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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, This Document Relates to: Debra Tinlin, et al. v. C. R. Bard, Inc., et al. CV-16-00263-PHX-DGC	No. 2:15-MD-02641-DGC **DEFENDANTS' TRIAL BRIEF** (Assigned to the Honorable David G. Campbell)

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Plaintiffs have nine remaining claims against Bard[1]: strict liability design defect (Count III), negligent design (Count IV), warnings-based claims (Counts II and VII), negligent and fraudulent misrepresentation/concealment (Counts VIII, XII, XIII), violation of Wisconsin law (Count XIV), loss of consortium (Count XV), and punitive damages.[2] Bard submits this Trial Brief to address certain of the legal issues that may arise at trial concerning Plaintiffs' claims.

I. Background

Wisconsin dramatically transformed its product liability law in 2011 in what legislators, courts, and commentators characterized as a "sea change." At that time, Wisconsin enacted Wis. Stat. § 895.047, which replaced Wisconsin's prior consumer expectations test for strict product liability design defect claims with the reasonable alternative design and risk-utility standards set forth Restatement (Third) of Torts: Product Liability § 2(b) (hereinafter "§ 2(b)"). For a more detailed discussion of the Wisconsin statute's background, *see* Bard's Trial Brief filed in *Hyde* at Docket No. 12358, at pages 1-2, which Bard incorporates herein. (*See also* Hyde Order on MILs [Dkt. No. 12507] at 3-5 (discussing the history of Wisconsin product liability law and the state's enactment of Wis. Stat. § 895.047).)

II. Wis. Stat. § 895.047 Applies to Plaintiffs' Strict Liability Design Defect Claim.

The Wisconsin product liability statute, Wis. Stat. § 895.047, provides as follows:

> (1) In an action for damages caused by a manufactured product based on a claim of strict liability, a manufacturer is liable to a claimant if the claimant establishes all of the following by a preponderance of the evidence:
>
> (1)(a) . . . A product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe. . . .

[1] Plaintiffs previously agreed to withdraw their claims for manufacturing-related issues (Counts I,V), negligent failure to recall/retrofit (Count VI), negligence per se (Count IX), breach of express warranty (Count X), and breach of implied warranty (Count XI).

[2] Bard addresses Plaintiffs' claims for misrepresentation/concealment, violation of Wisconsin law, loss of consortium, and punitive damages in the Pretrial Order.

(1)(b) That the defective condition rendered the product unreasonably dangerous to persons or property.

(1)(c) That the defective condition existed at the time the product left the control of the manufacturer.

(1)(d) That the product reached the user or consumer without substantial change in the condition in which it was sold.

(1)(e) That the defective condition was a cause of the claimant's damages.

A. Wis. Stat. § 895.047(1)(a) Applies a "Reasonable Alternative Design" Standard for Design Defect.

When Wisconsin passed Wis. Stat. § 895.047(1)(a), it adopted a reasonable alternative design standard for strict liability design defect cases, rejecting the consumer expectations test as the sole test for design defect. As this Court previously concluded, "a plaintiff claiming strict product liability under Wisconsin law must now show that the product's foreseeable risk of harm could have been reduced or avoided by a reasonable alternative design, and that the failure to adopt the alternative design rendered the product 'not reasonably safe.' § 895.047(1)(a)." (Hyde Order on MILs [Dkt. No. 12507] at 5.)

For a detailed discussion of the legislative, textual, extrinsic, and judicial support for this conclusion, *see* Bard's Trial Brief filed in *Hyde* at Docket No. 12358, at pages 3-9, which Bard incorporates herein.

B. A Reasonable Alternative Design Must Not Be a Completely Different Product, a Product Lacking a Key Design Feature, or a Defective Product.

A different product—even if similar to and serving the same purpose as the product at issue—cannot constitute a reasonable alternative design. *See generally Barnes v. Medtronic, PLC*, Case No. 2:17-cv-14194, 2019 WL 1353880, at *2 (E.D. Mich. March 26, 2019) ("In jurisdictions requiring plaintiffs to prove the existence of a safer alternative design, a design for a different, albeit similar, product will not suffice, even if it serves the same purpose." (internal quotation marks and citation omitted)); *see, e.g.*, *Hosford v. BRK Brands, Inc.*, 223 So.3d 199 (Ala. 2016) ("[D]ual-sensor smoke alarms" are not reasonable alternative designs to "ionization smoke alarms," noting that "a design for a

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different, albeit similar, product, even if it serves the same purpose" is not a reasonable alternative design); *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379 (Tex. 1995) (loader with a permanently installed rollover protective structure was not a reasonable alternative design for a loader with a removable rollover protective structure because the permanent product could not fulfill the multi-purpose roll of the loader with a removable structure); *Niedner v. Ortho-McNeil Pharm., Inc.*, 58 N.E.3d 1080, 1087 (Mass. Ct. App. 2016) (oral contraceptives are not a reasonable alternative design to a patch contraceptive even though both products are hormonal contraceptives that prevent pregnancy); *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760 (Tex. App. 2009) (Wyeth's predecessor product (Premarin), which had the same essential purpose as Wyeth's allegedly defective product (Prempro)—namely, to treat menopausal symptoms—was not a reasonable alternative design to Prempro because the two medications were different products and because Prempro could be useful in populations of patients that Premarin was not); *Massa v. Genentech, Inc.*, No. H-11-70, 2012 WL 956192 (S.D. Tex. Mar. 19, 2012) (applying Texas law) (holding that the plaintiff failed to establish alternative design by pointing to the existence of "competitive" products, even though the competitive products served "the same general purpose as the allegedly defective product"—because an alternative design must be for the same product rather than "a substantially different product").

Similarly, an alternative product that removes a key benefit or design attribute of the allegedly defective product—for instance, the ability to percutaneously retrieve an optional IVC filter—cannot serve as a reasonable alternative design. *Cf. Oden v. Boston Sci. Corp.*, CV 18-0334 (SJF)(SIL), 2018 U.S. Dist. LEXIS 102639, at **12-13 (E.D.N.Y. June 4, 2018) (retrievable IVC filter that did not have benefit of filter at issue—i.e., permanency—could not be reasonable alternative design in case involving permanent filter); *see also Quintana v. B. Braun Med. Inc.*, No. 17-CV-06614 (ALC), 2018 WL 3559091, at *5, n. 5 (S.D.N.Y. July 24, 2018) ("[A]ssuming such a requirement [for an alternative design at the pleading stage] is appropriate, it is clear that a retrievable filter,

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the only alternative design Plaintiff alleges, is not an appropriate comparator [to permanent filter at issue].").

Finally, a defective product cannot be a reasonable alternative design. *Tunnell v. Ford Motor Co.*, 385 F. Supp. 2d 582, 586 (W.D. Va. 2005) ("[T]he necessity of establishing that a proposed alternative design would satisfy the risk-benefit analysis is a matter of common sense. . . . Without such evidence, it is impossible to determine whether the proposed alternative design would truly cure a product of its alleged defect, or instead merely substitute one defect for another. One need not refer to the Third Restatement, academic commentary, or interpretive decisions to understand this basic point.").

C. Consumer Expectations Should Not Be a Factor Under Wis. Stat. § 895.047(1)(a) to Determine Product Defectiveness.

The Comments to § 2(b) provide this Court with guidance for interpreting Wis. Stat. § 895.047(1)(a). (*See* Bard's Trial Brief filed in *Hyde* Dkt. No. 12358] at 7-9, which Bard incorporates herein.) For instance, Comment f provides this Court with a "broad range of factors [that] may be considered in determining whether an alternative design is reasonable and whether its omission renders a product not reasonably safe." § 2, cmt. f (1998).

Bard recognizes Comment f identifies one factor as "the nature and strength of consumer expectations regarding the product, including expectations arising from product portrayal and marketing." § 2, cmt. f (1998). Additionally, Comment g states that while "consumer expectations do not play a determinative role in determining defectiveness . . . consumer expectations about product performance and the dangers attendant to product use affect how risks are perceived and relate to foreseeability and frequency of the risks of harm, both of which are relevant under Subsection (b)." § 2, cmt. g (1998).

Although Justice Diane Sykes believed that "consumer expectations are relevant but not dispositive" under § 2(b), *Green v. Smith & Nephew*, 629 N.W.2d 727, 768 (Wis. 2001) (Sykes, J., dissenting), Bard respectfully suggests that it is unclear, at best, whether

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the Wisconsin Supreme Court would adopt the consumer expectations portion of comment f, or any part of comment g to § 2(b). Notably, neither Justice Sykes in *Green*, nor Justice Prosser in *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 768 N.W.2d 674 (Wis. 2009) (Prosser, J., concurring), nor Justice Gableman in *Horst v. Deere & Co.*, 769 N.W.2d 536, 557 (Wis. 2009) (Gableman, J., concurring) cite to comment g when advocating for the adoption of § 2(b). Additionally, this Court noted that Wisconsin's adoption of Wis. Stat. § 895.047(1)(a) "effectively overruled" *Green*'s holding that the consumer expectations test is the sole test for product defectiveness. (Hyde Order on MILs [Dkt. No. 12507] at 5.[3])

Moreover, given how clear (a) Justice Prosser was in *Godoy* that the consumer expectations test "makes little or no sense in the context of defective design claims," *Godoy*, 768 N.W.2d at 696, (b) the majority in *Green* acknowledged that § 2(b) "departs from the consumer-contemplation test," *Green*, 629 N.W.2d at 751, and (c) the legislative intent in enacting Wis. Stat. § 895.047(1)(a) was to "adopt[] what's called the reasonable alternative design test instead of what Wisconsin has which is the consumer contemplation test," testimony of Brian Hagedorn, Wis. Sen. Bill 1 (2011): *Public Hearing before Joint Committee on Judiciary, Ethics, Utilities, Commerce and Government*, January 11, 2011 (testimony of Brian Hagedorn, Chief Legal Counsel to Gov. Scott Walker), Bard suggests that the Wisconsin Supreme Court would likely reject the consumer expectations test altogether, even as a factor under the risk/benefit test.[4]

[3] Although this Court went on to say "the consumer contemplation test is now only one factor in determining whether the Bard filter was unsafe," (Hyde Order on MILs [Dkt. No. 12507] at 5), it also noted that "[a] Wisconsin district court has expressed doubt whether [consumer expectations play a role in determining defectiveness]," that "consumer expectations are, ***at most***, only one factor to be considered in the ultimate determination of whether the omission of a proposed alternative design renders a product not reasonably safe," and declined to decide the issue. (*Id.* at 6 n.4 (emphasis added).)

[4] If consumer expectations has any role at all in Wisconsin's product liability law, the "consumer" or "user" of a product in the prescription medical device context is the physician who uses the device. *See Hall v. Boston Sci. Corp.*, No. 2:12-cv-08186, 2015 WL 874760, at *6 (S.D. W. Va. Feb. 27, 2015) (applying Wisconsin law); *see also, e.g., Adams v. Synthes Spine Co.*, 298 F.3d 1114, 1117 (9th Cir. 2002) (applying Washington

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Indeed, in addressing this very issue, District Court Judge Rebecca Pallmeyer, who was overseeing a Zimmer knee implant MDL, questioned whether a continued application of the consumer expectations test and Comment g "is an accurate statement of the law in Wisconsin." *In re: Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 218 F. Supp. 3d 700, 723 (N.D. Ill. 2016) (applying Wisconsin law), *aff'd* 884 F.3d 746 (7th Cir. 2018).[5]

D. Wis. Stat. § 895.047(1)(b) Does Not Apply a Consumer Expectations Test.

Wisconsin's product liability statute also requires that a "defective condition render[] the product unreasonably dangerous" before a Plaintiff may recover. Wis. Stat. § 895.047(1)(b). The statute does not define "unreasonably dangerous" or identify what evidence is necessary to meet this standard. Nor has Bard's counsel located any Wisconsin appellate opinion interpreting this portion of the product liability statute.

An MDL court in Illinois, however, has applied § 895.047(1)(b). *See In re: Zimmer*, 218 F. Supp. 3d at 724–25, *aff'd* 884 F.3d 746 (7th Cir. 2018). In *Zimmer*, on a motion for summary judgment, the Illinois District Court addressed whether the plaintiffs presented sufficient evidence that the product at issue was unreasonably dangerous. Although the court did not squarely answer that question (because the court ruled that the plaintiff could not establish the foundational requirement of a reasonable alternative design), it did express "concerns about Plaintiffs' ability to establish that the [product's] design is unreasonably dangerous" based on the opinions of the plaintiffs' two proffered experts. *Id.* at 725. The court noted that the first expert did "not offer an opinion about the absolute risk" of the product "and thus can also offer no opinion about whether such a risk makes the [product] unreasonably dangerous." *Id.* Regarding the second expert, the court

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law) ("Under Washington law, the 'consumer' of a prescription-only medical device . . . is the physician, not the patient in whom it is installed . . . ."); *St. Clair v. Nellcor Puritan Bennett LLC*, No. CV-10-1275-PHX-LOA, 2011 WL 5331674, at *6–7 (D. Ariz. Nov. 7, 2011) (applying Arizona law) ("the consumers" in the consumer-expectations test for prescription medical devices are "the medical professionals who used the" device).

[5] In its *Hyde* Order on Motions *in Limine*, this Court recognized the uncertain role, if any, that consumer expectations plays under Wis. Stat. § 895.047(1)(a), but it declined to decide the issue. (Hyde Order on MILs [Dkt. No. 12507] at 6 n.4.)

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expressed concern that he had not "conducted a risk-benefit analysis" and could not opine whether the product was "unsafe." *Id.*

The *Zimmer* analysis suggests that whether a product is "unreasonably dangerous" under Wis. Stat. § 895.047(1)(b) turns on a "risk-benefit analysis" and the "absolute risk" of the product, not on what an ordinary user or consumer may expect from the device. Indeed, the *Zimmer* court's analysis of Wis. Stat. § 895.047(1)(b) makes no mention of consumer expectations at all. Thus, the one court to address the statute has, in essence, utilized a risk-benefit approach to determine whether the product is unreasonably dangerous under Wis. Stat. § 895.047(1)(b).[6]

That "unreasonably dangerous" no longer contemplates a consumer expectations test—thus rendering pre-2011 Wisconsin opinions inapplicable on this point because they have been superseded by statute—is consistent with Wisconsin's intent to exorcise consumer expectations entirely from Wisconsin's law. (*See* Bard's Trial Brief filed in *Hyde* [Dkt. No. 12358], at Section II.B and Section II.C.ii.(b) & Note 13, *supra*.)

E. Wis. Stat. § 895.047(3)(d) Precludes Liability for Damage Caused by an "Inherent Characteristic" of the Product.

Wis. Stat. § 895.047(3)(d) provides the following defense in a product liability action:

> (d) The court shall dismiss the claimant's action under this section if the damage was caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product.

Neither Wisconsin's products liability statute nor Wisconsin appellate decisions interpreting it define what "inherent characteristic" means. But, the defense is similar to a

[6] This is consistent with at least one other opinion from Iowa that found "unreasonably dangerous" to be pseudonymous with "not reasonably safe." *Ackerman v. Am. Cyanamid Co.*, 586 N.W.2d 208, 220 n.4 (Iowa 1998) ("Some of our later cases refer to the 'unreasonably dangerous' element as requiring proof that the product was not 'reasonably safe.'") (Ternus, J., concurring in part and dissenting in part).

pre-2011 common law defense recognized by the court in *Godoy*. 768 N.W.2d 674. That case involved design defect allegations concerning the presence of lead in white lead carbonate pigment. The court held that a "claim for defective design cannot be maintained where the presence of lead is the alleged defect in design, and its very presence is a characteristic of the product itself." *Id.* at 685; *see also id.* at 684 (comment h to § 402A "does not state that a defective condition can arise from harmful ingredients that ***are*** characteristic of the product" (emphasis in original)).[7]

In this case involving an IVC filter, the alleged "damage" to Plaintiffs was caused by the risk of filter fracture, which is an "inherent characteristic" associated with all IVC filters. If the risk of fracture were removed from an IVC filter, it would "transform it into a different product," *Godoy*, 768 N.W.2d at 684, because all IVC filters carry the risk of fracture.

Wis. Stat. § 895.047(3)(d) also does not identify who is the "ordinary person with ordinary knowledge common to the community that uses or consumes the product." But in the only court opinion that Bard's counsel could find that has applied this statutory defense, *Hall v. Boston Sci. Corp.*, No. 2:12-cv-08186, 2015 WL 874760 (S.D. W. Va. Feb. 27, 2015), in a prescription medical device case, the MDL judge considered the "ordinary person" to be the physician using the product, and not the patient. *Id.* at *6. While the parties in *Hall* "assume[d] that an 'ordinary' user for purposes of § 895.047 is the implanting physician," *id.* at *6 n.2, that assumption makes sense in light of the plain language of the statute, which references "the community that uses or consumes the product." Wis. Stat. § 895.047(3)(d). Patients are not a community that use IVC filters, but physicians are. Thus, it is the "ordinary" user of IVC filters—i.e., a physician who

[7] Because *Godoy* was decided before Wis. Stat. § 895.047(3)(d) was enacted, "it is not clear to what extent *Godoy* controls today." *Hall*, 2015 WL 874760, at *5. But because the defense in Wis. Stat. § 895.047(3)(d) is "similar to the one articulated by the *Godoy* court," and because the statute "does not indicate whether it replaces the common law or merely supplements it," a court should interpret the statute "in light of *Godoy*." *Hall*, 2015 WL 874760, at *5.

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implants IVC filters—whose knowledge is relevant to the application of Wis. Stat. § 895.047(3)(d). *Cf., e.g., St. Clair*, 2011 WL 5331674, at *7 (in medical device case, "the ordinary consumer under the consumer expectation test is the physician who used the [product]"); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 751 (E.D. Pa. 2007) ("the intended user" of medical device "is the prescribing physician").

In *Hyde*, Bard sought a jury instruction on this "inherent characteristic" defense, and the plaintiffs objected. After hearing arguments, this Court gave Bard's proposed instruction on the defense, finding "Defendants are entitled by Wisconsin law to have the defense included in the jury instructions." (*Hyde* Order [Dkt. No. 12810]; *Hyde* Final Jury Instructions [Dkt. No. 12824] at 15.)

III. Negligent Design Defect

To establish a claim of negligence, a plaintiff must prove the following elements:

(1) the existence of a duty of care on the part of the defendant,
(2) a breach of that duty of care,
(3) a causal connection between the defendant's breach of the duty of care and the plaintiff's injury, and
(4) actual loss or damage resulting from the injury.

Gritzner v. Michael R., 611 N.W.2d 906, 912 (Wis. 2000).

In the negligent design defect context, "manufacturers have a duty to 'exercise ordinary care in the design, construction, and manufacture' of their products." *Regent Ins. Co. v. Cincinnati Ins. Co.*, No. 14-C-1434, 2015 WL 7681254, at *3 (E.D. Wis. Nov. 24, 2015) (quoting Wis. JI-Civil 3240). The defendant manufacturer is held to the "'reasonable person' standard of customary methods of manufacture in a similar industry." *Morden v. Cont'l AG*, 611 N.W.2d 659, 675 (Wis. 2000). A manufacturer should conduct "all reasonable and adequate tests and inspections 'so as to guard against any defective condition which would render such product unsafe when used as it is intended to be used.'" *Regent*, 2015 WL 7681254, at *3 (quoting Wis. JI-Civil 3240). Whether a product is negligently designed and unsafe "turns essentially on whether the seller could have come up with a less dangerous design." *Below v. Yokohama Tire Corp.*,

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No. 15-CV-529-WMC, 2017 WL 679153, at *3 (W.D. Wis. Feb. 21, 2017) (internal quotation marks and citation omitted). But proving that "better methods of manufacture exist does not conclusively prove that a defendant created the product with a lack of ordinary care"; instead, the plaintiff must "prove that the defendant selected the more dangerous route of manufacture knowing that it was unsafe." *Morden*, 611 N.W.2d at 675. This inquiry requires a risk/benefit analysis. *See Meyer v. Val-Lo-Will Farms, Inc.*, 111 N.W.2d 500, 503 (Wis. 1961) ("Conduct constitutes negligence if the risk of harm involved is of such magnitude as to outweigh what the law regards as the utility of the act or the manner in which it is done."); *see also Green*, 629 N.W.2d at 751 (citing *Meyer* and stating in a parenthetical that "negligence claims require a risk-benefit analysis"); *Hyde* Order on MILs [Dkt. No. 12533] at 4 ("[I]n deciding Plaintiff's negligence claim, the jury will be required to decide whether Defendants acted reasonably in designing and releasing the filter. In making this determination, the jury may employ a risk-benefit analysis.").

Because manufacturers are held to the "reasonable person" standard of customary methods of manufacture in a similar industry, conformance or nonconformance with industry customs and the state of the art "provide[s] evidence to the jury about whether the defendant reasonably could have done something to prevent the harm." *Morden*, 611 N.W.2d at 675. Additionally, evidence of compliance with FDA regulations concerning medical devices—even in the context of a Class II medical device—is relevant to determine whether the manufacturer fulfilled its duty of care. *See Stevens v. Stryker Corp.*, No. 12-CV-63-bbc, 2013 WL 4758948 at *4 (W.D. Wis. Sept. 4, 2013) (allowing expert testimony concerning compliance with FDA regulations in Class II medical device case); *see also Hyde* Order on MILs [Dkt. No. 12533] at 3 (citing *Stevens* with the following parenthetical: "noting that the reasonableness of the manufacturer's conduct is informed by FDA regulations"). Finally, evidence regarding a manufacturer's post-market activities—such as Bard's communications with FDA regarding the Recovery Filter—are relevant to the question of whether [the manufacturer] acted reasonably for purposes of

the negligent design claim." (*Hyde* Order on MILs [Dkt. No. 12533] at 2.)

Regarding causation, that element "turns on whether the defendant's negligence was a substantial factor in producing the injury." *Morden*, 611 N.W.2d at 676 (internal quotation marks and citation omitted). "[C]ausation focuses on the nexus between the design or manufacture of the [product at issue] and [the plaintiff's] injuries." *Id.* Whether a sufficient "nexus" exists turns on whether the defendant's actions were a "cause-in-fact" and the "proximate cause" of the plaintiff's injuries. *Id.*

IV. Failure to Warn

A. The Wisconsin Supreme Court Would Adopt the Learned Intermediary Doctrine.

In *In re Zimmer, NexGen Knee Implant Products Liability Litigation*, 884 F.3d 746 (7th Cir. 2018), the Seventh Circuit recently analyzed whether the Wisconsin Supreme Court would adopt the learned intermediary doctrine. As the court discussed, the weight of authority in Wisconsin[8] strongly suggests that it would. Indeed, the only Wisconsin court to decline application of the learned intermediary doctrine incorrectly noted that "Wisconsin does not apply the learned intermediary doctrine," and offered no analysis about the issue. *Id.* at 751 (citing *Maynard v. Abbott Labs.*, No. 12-C-0939, 2013 WL 695817 (E.D. Wis. Feb. 26, 2013)). The Seventh Circuit reasoned that at least 48 states' highest courts or intermediate appellate courts have applied or favorably cited the learned

[8] *Monson v. Acromed Corp.*, No. 96-C-1336, 1999 WL 1133273 at *20 (E.D. Wis. May 12, 1999) (applying Wisconsin law, holding that under the learned-intermediary doctrine, "the manufacturer must warn the physician . . . and not the patient directly"); *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (applying Wisconsin law) ("under the Learned Intermediary Doctrine, manufacturers of prescription medical products have a duty only to warn physicians, rather than patients, of the risks associated with the use of the product"); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 963 (E.D. Wis. 1981), *amended*, 532 F. Supp. 211 (E.D. Wis. 1981). Further, a Wisconsin state trial court has followed this rule and recognized that "courts of numerous other jurisdictions almost universally hold that in the case of prescription drugs, a manufacturer's provision of proper warnings to a prescribing physician will satisfy the manufacturer's duty to warn since the patient cannot obtain the drug except through the physician." *Straub v. Berg*, Nos. 00-CV-2100, 00-CV-0117, 2003 WL 26468454 at *6 (Wis. Cir. Jan. 6, 2003) (citation omitted).

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intermediary doctrine and that the rationale "applies even more forcefully in cases involving surgical implants" because patients cannot obtain and implant such devices without the intervention and training of a physician. *Id.* at 751-52. The Seventh Circuit concluded, "[i]n short, there is good reason to think that given the opportunity, the Wisconsin Supreme Court would join the vast majority of state supreme courts and adopt the learned-intermediary doctrine for use in defective-warning cases like this one involving a surgical implant. We predict that the state high court would do so." *Id.* at 752.

B. A Failure-to-Warn Claim Requires Proof That a Different Warning Would Have Changed The Learned Intermediary's Decision to Use the Product.

Causation is a necessary element of a failure-to-warn claim. In the context of a prescription medical device case where the learned intermediary doctrine applies, the plaintiff must prove that a different warning would have changed the learned intermediary's decision to use the product. *See* Wis. Stat. § 895.047 (1)(e) (requiring a plaintiff to prove that "the defective condition was a cause" of her injuries); *Kessel ex rel. Swenson v. Stansfield Vending, Inc.*, 714 N.W.2d 206, 211-12 (Wis. Ct. App. 2006) (a plaintiff claiming negligent failure to warn must prove "a causal connection between the defendant's breach of the duty of care and the plaintiff's injury"); *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 876 (Wis. Ct. App. 2004) ("Absent proof that a more complete or explicit warning would have prevented [plaintiff's] use of [defendant's product], she cannot establish that [defendant's] alleged failure to warn was the proximate cause of her injuries."); *see also In re Bard IVC Filters Prod. Liab. Litig.*, No. CV-16-00893-PHX-DGC, 2018 WL 3586404, at *9 (D. Ariz. July 26, 2018) (applying Wisconsin law, granting summary judgment on failure to warn claims involving G2X or Eclipse filter where there was "no evidence that Mrs. Hyde or Dr. Henry would have acted differently in the face of different warnings by Bard"); *Hanson v. Boston Sci. Corp.*, No. 2:13-CV-10653, 2016 WL 1448868, at *5 (S.D.W. Va. Apr. 12, 2016) (applying Wisconsin law, and finding causation evidence insufficient where it "require[d] a reasonable juror to

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speculate, based only on mere *possibility*, that [the doctor] would have altered her decision to prescribe the product simply because she would have *considered* an additional factor in her risk/benefit calculus" (emphasis in original)); *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (applying Wisconsin law, and finding that "a plaintiff must not only show that a manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff").

RESPECTFULLY SUBMITTED this 12th day of April, 2019.

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